

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 09/01/2011

FORM APPROVED

OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15C0001073		(X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		(X3) DATE SURVEY COMPLETED 07/27/2011	
NAME OF PROVIDER OR SUPPLIER RIVERPOINTE SURGERY CENTER				STREET ADDRESS, CITY, STATE, ZIP CODE 500 ARCADE AVE STE 100 ELKHART, IN46514			
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S0000	The visit was for a licensure survey. Facility Number: 009967 Survey Date: 07-25-11 to 07-27-11 Surveyors: Brian Montgomery, RN Public Health Nurse Surveyor Linda Plummer, RN Public Health Nurse Surveyor Karilyn Tretter, RN Public Health Nurse Surveyor QA: cloughlin 08/15/11			S0000			
S0132	410 IAC 15-2.4-1 (b)(8) The governing body shall do the following: (8) Ensure surgical procedures are performed only by a physician, dentist, or podiatrist who is privileged to perform such procedures according to medical staff bylaws, regulations, and/or policies and procedures.						

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (see instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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	<p>Based upon document review and interview, the governing body failed to ensure that surgical procedures at the center were only performed by physicians privileged by the governing body for 1 of 9 physicians at the center.</p> <p>Findings:</p> <p>1. Review of the medical credential file for physician #9 indicated that the last reappointment had occurred on 10-23-2007 for two years and the surgical privileges expired 10-31-2009.</p> <p>2. On 07-27-2011 at 1215 hours, employee #A6 was requested to provide a list of surgical cases performed by physician #9 in 2011. Review of the requested information indicated that 20 surgical cases were performed in 2011.</p> <p>3. On 07-27-11 at 1300 hours, employee #A1 confirmed that physician #9 was in the process of being recredentialed.</p>		S0132	<p>1. Plan offi Correctton The physician was granted ttemporary privileges on August16, 2011 The dattes offi reappointmentt and otther key dattes offi license expiratton and DEA expiratton will be entered into a ttracking calendarA reportt will be reviewed every montht ffior any ittemts due tto expire witht90 days so tthatt tthe updatte can be obtained and processed prior tto expiratton Exhibitt(s) Temporary privileges approval letter Calendar example with expiratton dattes</p> <p>2. Preventton: Monittoring offi tthe use offi tthe calendar ttracking soffware and periodic auditt offi credenttaling ffirmms</p> <p>3. Responsible partty Executtve Assitttantt</p> <p>4. Correctton Completted</p> <p>a. Temporary privileges granted on Augustt16, 2011 b. Presentt to Board ffior reappointtmentt att Board meettng on Septtember1, 2011</p>		08/16/2011	

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S0162	<p>410 IAC 15-2.4-1 (c)(5) (G)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p> <p>(G) Ensuring cardiopulmonary resuscitation (CPR) competence in accordance with current standards of practice and center policy for all health care workers including contract and agency personnel, who provide direct patient care.</p> <p>Based on personnel file review and job descriptions, the facility failed to ensure CPR competence according to facility policy for 4 of 6 (P1, P3, P4, P5) ASC employees.</p> <p>Findings include:</p> <p>1. During personnel file review on 7/26/2011, there was no documentation that P1 (a pre-op/post-op RN) was competent in PALS (Pediatric Advanced Life Support). Job description for Perioperative Registered Nurse includes "Minimal knowledge, skills, and abilities required: 1. Current CPR Certification. ACLS and PALS Certification."</p> <p>2. During personnel file review on 7/26/2011, there was no documentation that P3 (a sterilization tech) was competent in CPR (Cardiopulmonary Resuscitation). Job description for Sterilization Tech (Surgery Assistant) includes "Maintains all required certifications (CPR)."</p> <p>3. During personnel file review on 7/26/2011, there was no documentation that P4 (a pre-op/post-op RN) was competent in ACLS (Advance Cardiac Life Support). Job</p>		S0162	<p>1. Plan offi Correctton Job descriptttons were changed tto allow tthe RNs tto obtain PALS and ACLS withtin6 monthts offi hire A check listt was estblished tto confirm thhatt all clinical sttaffiaving directt patientt care, whether contracttagency personnel, or employed by tthe surgery center have currentt CPR compettency Exhibitt(s) Job descripttton offi RN Listt tto track materialts tto have in ffile</p> <p>2. Preventton: Check listt ffor employee ffile tto include verifficatton offi CPR prior tto datte offi ffirstt assignmentt offi directt patientt care.</p> <p>3. Responsible Partty Executtve Assistantt</p> <p>4. Correctton Completed August26, 2011</p>		08/26/2011	

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S0166	<p>description for Perioperative Registered Nurse includes "Minimal knowledge, skills, and abilities required: 1. Current CPR Certification. ACLS and PALS Certification."</p> <p>4. During personnel file review on 7/26/2011, there was no documentation that P5 (a pre-op/post-op RN) was competent in BLS (Basic Life Support), ACLS, or PALS. Job description for Perioperative Registered Nurse includes "Minimal knowledge, skills, and abilities required: 1. Current CPR Certification. ACLS and PALS Certification."</p> <p>410 IAC 15-2.4-1 (c)(5) (I)</p> <p>Require that the chief executive officer develop and implement policies and programs for the following:</p> <p>(I) Requiring all services to have policies and procedures that are updated as needed and reviewed at least triennially.</p> <p>Based upon document review and interview, the facility failed to ensure the review of all policies/procedures was performed triennially and failed to ensure a policy/procedure for verifying illegible information in the patient record.</p> <p>Findings:</p>			S0166	<p>1. Plan offi Correctton</p> <p>Policy written tto review policies and procedures annually tto assure updattes tto regulattons and sttandards are completted and sttaffi is educatted Policy written tto address whatt sttaffi is tto do iffi writting on medical record is nott legible Exhibitt(s)</p> <p>Policy tto review and updatte policies and procedures annually</p>		08/26/2011

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	<p>1. Review of the facility policies/procedures manuals failed to indicate a review had been performed by the administrator or another responsible party in the last three years.</p> <p>2. On 07-26-2011 at 0825 hours, employee #A6 confirmed that the facility had failed to review all of its policies/procedures during the last three years and that the facility lacked a policy/procedure requiring a triennial review of all policies/procedures by an individual or a committee.</p> <p>3. The policy/procedure Medical Records and Documentation (revised 04-11) failed to indicate a process for verifying information with questionable legibility in the MR.</p> <p>4. On 07-26-2011 at 1500 hours, employee #A6 confirmed the facility lacked a policy/procedure for verifying illegible information in the patient record.</p>				<p>Policy offi whatt sttaffi is tto do tto veriffiy inffiormatton when illegible tto tthe reader</p> <p>2. Preventton: An annual calendar offi whatt mustt be presentted tto tthe governing body will be esttablished and marked offi when completted tto assure policies are reviewed, updatted as needed and presentted tto tthe governing body ffor approval.</p> <p>3. Responsible Person(s): Executtve Assistantt</p> <p>4. Correctton Completted</p> <p>a. Policies written by Augustt26, 2011</p> <p>b. Presentted ffor approval att Governing Body meettng Septtember 1, 2011</p>		

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S0212	<p>410 IAC 15-2.4-1(d)(2)(A & B)</p> <p>(d) In accordance with center policy, the governing body shall do the following:</p> <p>(2) Ensure the following:</p> <p>(A) The center develops, implements, and maintains written medical staff policies and procedures for emergencies, initial treatment, and transfer.</p> <p>(B) The center provides immediate lifesaving measures within the scope of service available, to all persons in the center, to include, but not be limited to, the following:</p> <p>(i) Timely assessment. (ii) Basic life support. (iii) Proper transfer mode.</p> <p>Based on policy and procedure review, patient medical record review and staff interview, the governing board failed to ensure that staff implemented the facility transfer policy for 3 of 5 transfer patients (N1, N3, and N14).</p> <p>Findings:</p> <p>1. at 4:40 PM on 7/25/11, review of the policy and procedure "Transfers, Hospital" with a policy number of CT-01 and a last revision date of 04/05, indicated:</p> <p>a. under "Procedure:", it read: "Emergency Transfers:...3. One copy of</p>			S0212	<p>1. Plan offi Correctton Staffi will use a pattentt ttransffier log tthatt will include tthe name offi tthe pattentt reason ffior ttransffier discharge summary obtained ttransffier record in medical record and tthe datte tthe ttransffier is sentt ffior peer review.</p> <p>The ttransffier ffform will now include a ttextt box to remind tthe person completng tthe ffform thatt tthe original sttays in tthe medical record and a copy is routted to QIC Coordinattor Exhibitt(s) Transffier log Transffier ffform</p>		08/26/2011

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S0230	<p>the chart is made for the hospital. Transfer form will be completed and a copy will be retained for the Clinical Director..."</p> <p>2. review of patient medical records through out the survey process of 7/25/11 to 7/27/11 indicated:</p> <p>a. patients N1, N3 and N14 were transfer patients who were lacking a transfer form in their medical records</p> <p>3. interview with staff member ND at 11:00 AM on 7/27/11 indicated:</p> <p>a. transfer forms should have been completed for patients N1, N3 and N14, per facility policy</p> <p>410 IAC 15-2.4-1(e)(5)</p> <p>The governing body is responsible for services delivered in the center whether or not they are delivered under contracts. The governing body shall do the following:</p> <p>(5) Provide for a periodic review of the center and its operation by a utilization review or other committee composed of three (3) or more duly licensed physicians having no financial interest in the facility.</p>				<p>2. Preventton: A monthly auditt tto compare ttransfer records received with clinical log and complicaatton reportts received will be conductted tto assure QIC receives tthe ttransfer recorddthe clinical log is correctly statatng tthe discharge sttattusand tthe complicaatton reportts are correctt</p> <p>3. Responsible Person(s): QIC Coordinattor</p> <p>4. Correctton Completed</p> <p>a. Policy written by Augustt26, 2011</p> <p>b. Presentted tto governing body ffor approval on Septtember, 2011</p>		

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	<p>Based upon document review and interview, the governing board failed to ensure a periodic review of the center was performed by a committee composed of a minimum of 3 physicians who do not have a financial interest in the facility.</p> <p>Findings:</p> <p>1. The RiverPointe Surgery Center Board of Managers bylaws (last approved 7-2010) indicated the following: [The Board shall] Provide for a periodic review of The Center and its operation by a Utilization Review Committee composed of a minimum of three licensed physicians who have evidenced their lack of financial interest in The Center.</p> <p>2. The RiverPointe Surgery Center Medical Staff Bylaws (last reviewed/approved 07-28-2010) indicated the following; The Medical Quality Improvement Committee (MQIC) shall conduct ... utilization review studies, as necessary, designed to evaluate the appropriateness of surgery and use of the Center services...[and]...A quorum of the MQIC shall be the Medical Director or his designee and two other members.</p> <p>3. The Medical Quality Improvement Program (revised 04-05) failed to indicate</p>			S0230	<p>1. Plan of Correction: Three physicians who are non-investors in the surgery center will be appointed to serve on a utilization review committee. The Medical Staff Bylaws will be reviewed and clarified if needed to address the responsibilities for peer review. Exhibit(s) Appointment of three physicians</p> <p>2. Prevention: Review of utilization review activities will be conducted and presented quarterly to the Governing Body</p> <p>3. Responsible Person(s): Executive Assistant</p> <p>4. Correction Completed: a. Bylaws will be reviewed by August 31, 2011 b. Potential members for Utilization Review Committee membership will be contacted before August 26, 2011 c. Membership and committee responsibilities will be presented to governing body at September 1, 2011 meeting</p>		08/31/2011

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S0310	<p>that Utilization Review will be conducted by at least 3 licensed physicians who do not have a financial interest in The Center.</p> <p>4. During an interview on 07-26-2011 at 1013 hours, employee #A1 indicated that only two licensed physicians (MD #10, MD# 11) attended the MQIC meetings and did not have a financial interest in the facility.</p> <p>410 IAC 15-2.4-2(a)(1)</p> <p>The program shall be ongoing and have a written plan of implementation that evaluates, but is not limited to, the following:</p> <p>(1) All services, including services furnished by a contractor.</p> <p>Based on document review and interview, the facility failed to monitor one direct service (radiology) and 7 contracted services (bioengineering, biohazardous waste, housekeeping, laboratory, laundry, maintenance, and medical transcription) through its Quality Improvement program.</p> <p>Findings:</p> <p>1. The policy/procedure Medical Quality Improvement Program (revised 04-05) indicated the following: There shall exist</p>			S0310	<p>1. Plan offi Correctton</p> <p>The QIC Coordinattor has developed a system tto gattther infformatton and reportt on services ffiurnished by outside contracttorsThe infformatton will be reportedt to the Governing Body with acttoas needed, tto adjustt service delivery or contracttorsThe Governing Body will be presentted tthe evaluatton and reporttng ffiorm att tthe Septemler board meettng.</p> <p>Exhibitt(s)</p> <p>Evaluatton and reporttng ffiorms</p> <p>Policy</p>		08/26/2011

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	<p>at the Center an organized program to improve the quality of care and promote more effective and efficient utilization of facilities and services.</p> <p>2. Review of the Medical Quality Improvement, Risk Management, and Peer Review Committee minutes for 2010 and 2011 failed to indicate documentation of periodic monitoring and reporting for the direct service of radiology and the 7 contracted services of bioengineering, biohazardous waste, housekeeping, laboratory, laundry, maintenance, and medical transcription for the facility.</p> <p>3. During an interview on 07-26-2011 at 1630 hours, employees #A4 and #A6 confirmed the facility was not monitoring the services indicated above.</p>				<p>2. Prevention: The QIC coordinator will review the service delivery off outside contractors and consultants and report findings to the Board</p> <p>3. Responsible Person(s): QIC Coordinator Executive Assistant</p> <p>4. Correction Completed</p> <p>a. Policy and forms developed by August 26, 2011</p> <p>b. Presented to governing body for approval at meeting off September 1, 2011</p>		

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S0334	<p>410 IAC 15-2.4-2.2(a)(2)</p> <p>(2) A process for reporting to the department each reportable event listed in subdivision (1) that is determined by the center's quality assessment and improvement program to have occurred within the center.</p> <p>(b) Subject to subsection (e), the process for determining the occurrence of the reportable events listed in subsection (a)(1) by the center's quality assessment and improvement program shall be designed by the center to accurately determine the occurrence of any of the reportable events listed in subsection (a) (1) within the center in a timely manner.</p> <p>(c) Subject to subsection (e), the process for reporting the occurrence of a reportable event listed in subsection (a)(1) shall comply with the following:</p> <p>(1) The report shall:</p> <p>(A) be made to the department;</p> <p>(B) be submitted not later than fifteen (15) working days after the reportable event is determined to have occurred by the center's quality assessment and improvement program;</p> <p>(C) be submitted not later than four (4) months after the potential reportable event is brought to the program's attention; and (D) identify the reportable event, the quarter of occurrence, and the center, but shall not include any identifying information for any:</p> <p>(i) patient;</p> <p>(ii) individual licensed under IC 25; or</p> <p>(iii) center employee involved;</p> <p>or any other information.</p> <p>(2) A potential reportable event may be identified by a center that:</p> <p>(A) receives a patient as a transfer; or</p> <p>(b) admits a patient subsequent to discharge; from another health care facility subject to a reportable event requirement. In the event</p>						

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	<p>that a center identifies a potential reportable event originating from another health care facility subject to a reportable event requirement, the identifying center shall notify the originating health care facility as soon as they determine an event has potentially occurred for consideration by the originating health care facility's quality assessment and improvement program.</p> <p>(3) The report, and any documents permitted under this section to accompany the report, shall be submitted in an electronic format, including a format for electronically affixed signatures.</p> <p>(4) A quality assessment and improvement program may refrain from making a determination about the occurrence of a reportable event that involves a possible criminal act until criminal charges are filed in the applicable court of law.</p> <p>(d) The center's report of a reportable event listed in subsection (a)(1) shall be used by the department for purposes of publicly reporting the type and number of reportable events occurring within each center. The department's public report will be issued annually.</p> <p>(e) Any serious reportable listed in subsection (a)(1) that:</p> <p>(1) is determined to have occurred within the center between:</p> <p>(A) January 1, 2009; and</p> <p>(B) the effective date of this rule; and</p> <p>(2) has not been previously reported; must be reported within five (5) days of the effective date of this rule. (Indiana State Department of Health; 410 IAC 15-2.4-2.2)</p> <p>Based on policy and procedure review, incident/event report review and staff interview, the facility failed to ensure that a policy related to reportable events</p>			S0334	<p>1. Plan of Correction: A policy will be developed and staff educated about the adverse events and the reporting of events. The Medical Director will</p>		08/26/2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 09/01/2011

FORM APPROVED

OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 15C0001073		(X2) MULTIPLE CONSTRUCTION A. BUILDING 00 B. WING _____		(X3) DATE SURVEY COMPLETED 07/27/2011	
NAME OF PROVIDER OR SUPPLIER RIVERPOINTE SURGERY CENTER				STREET ADDRESS, CITY, STATE, ZIP CODE 500 ARCADE AVE STE 100 ELKHART, IN46514			
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	existed. Findings: 1. at 12:30 PM on 7/26/11, review of facility incident reports indicated: a. a pt. wrong site surgery had been documented on an event/incident report in May 2010 b. the facility did not report this to the State as per the reportable events rule 2. review of policies and procedures through out the survey process of 7/25/11 to 7/27/11 indicated: a. the facility did not have a policy related to adverse events that are reportable to the State 3. interview at 12:30 PM on 7/26/11 with staff members NB and ND indicated: a. it was unknown that there was a list of reportable adverse events in the state rules that are required to be reported to the State				also educate the medical staff via written and verbal communication of the responsibility to assess an occurrence. The policy will include the process for review by the quality assessment and improvement program and reporting to the state as required by regulations.Exhibit(s)Policy on reporting events2. Prevention: Employees and medical staff will receive education in September and annually about reporting requirements. 3. Responsible Person(s): QIC Coordinator 4. Correction Completed: a. Policy will be written by August 26, 2011b. Policy presented to Governing Body for approval on September 1, 2011		

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S0606	<p>410 IAC 15-2.5-3(b)(1)</p> <p>(b) The organization of the medical record service must be appropriate to the scope and complexity of the services provided as follows:</p> <p>(1) The services must be directed by a registered record administrator (RRA) or an accredited record technician (ART). If a full-time and/or part-time RRA or ART is not employed, then a consultant RRA or ART must be provided to assist the qualified person in charge. Documentation of the findings and recommendations of the consultant must be maintained.</p> <p>Based upon document review and interview, the facility lacked a qualified medical records (MR) director for their MR department.</p> <p>Findings:</p> <p>1. On 07-25-2011 at 1130 hours, employee #A2 was requested to provide documentation including a personnel file for the Registered Health Information Technician (RHIT) or Registered Health Information Administrator (RHIA) qualified director of medical records and none was provided prior to exit.</p> <p>2. On 07-26-2011 at 1340 hours, employee #A6 was requested to provide a policy/procedure or job description</p>			S0606	<p>1. Plan offi Correctton An agreementt with a consultantnt RHIT/RHIA was signed Augustt23, 2011 Exhibitt(s) Agreementt with RHIT/RHIA Policy regarding an agreementt with an RHIT/RHIA Tracking and evaluatting outtside service agreementts; RHIT/RHIA included.</p> <p>2. Preventton: An agreementt with an RHIT/RHIA will be contnued, renewed, and monitted</p> <p>3. Responsible Person(s): Executtve Assistantt</p> <p>4. Correctton Completed</p>		08/26/2011

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S0624	<p>indicating that the MR department was directed by RHIT or RHIA professional and none was provided prior to exit.</p> <p>3. On 07-27-2011 at 1100 hours, employee #A3 indicated that an agreement with a consultant RHIT/RHIA providing medical records oversight had expired in 2007 and the facility failed to have an agreement with a qualified professional at the present time.</p> <p>410 IAC 15-2.5-3(c)(7)</p> <p>An adequate medical record must be maintained with documentation of service rendered for each patient of the center as follows:</p> <p>(7) The center shall ensure the confidentiality of patient records. The center must develop, implement, and maintain the following:</p> <p>(A) A procedure for releasing information or copies of records only to authorized individuals, in accordance with federal and state laws.</p> <p>(B) A procedure that ensures that unauthorized individuals cannot gain access to patient records.</p> <p>Based upon document review, observation and interview, the facility failed to ensure that medical records (MR) were not accessible to unauthorized individuals.</p>			S0624	<p>a. Agreement completed August 23, 2011</p> <p>b. Process of tracking off agreement and evaluation progress completed by August 26, 2011</p> <p>c. Board approval of agreement and outside service contract evaluation system at September 4, 2011</p> <p>1. Plan of Correction Policies on the protection of medical records have been written and implemented. The cleaning staff will have access to the medical record areas only when that area is staffed or</p>		08/26/2011

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	<p>Findings:</p> <ol style="list-style-type: none"> Review of the policy/procedure Medical Records, Protected Health Information, Need to Know (revised 04-05) failed to indicate how the facility provided physical barriers to limit access to MR by unauthorized individuals at the facility. During a facility tour of medical records storage on 07-25-2011 at 1430 hours, accompanied by employees #A2 and #A6, large rolling file stacks without lockable covers or barriers to prevent unauthorized access to protected health information were observed in the administrative offices at the facility. During a facility tour of medical records storage on 07-25-2011 at 1430 hours, accompanied by employees #A2 and #A6, five cardboard MR storage boxes containing patient records awaiting transport to an archive service were observed in the area adjacent to the rolling file stacks. During an interview on 07-25-2011 at 1430 hours, employee #A6 indicated that the contracted housekeeping services cleaned the areas where MR were stored in the evening when other facility staff 				<p>only when the file area is contained to prevent access. Any temporary storage off records awaiting digital storage will be locked and boxes clearly marked to note that the records are not AP or AR files and require access protection.</p> <p>Exhibit(s) Policy on protection off records</p> <ol style="list-style-type: none"> Prevention: Staff will be educated on limited access to the medical record area. The cleaning staff access will be restricted and monitored. The file storage area will be reviewed for ability to lock racks to prevent access. Responsible Person(s): Business Office Manager Correction Completed <ol style="list-style-type: none"> Complete restricted access to area by cleaning staff by August 6, 2011 Present policies and procedures approval to governing body on September 1, 2011 Complete assessment off ability to lock rolling file area by September 9, 2011 		

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S0772	<p>were not present.</p> <p>410 IAC 15-2.5-4(b)(3)(M)</p> <p>These bylaws and rules must be as follows:</p> <p>(3) Include, at a minimum, the following:</p> <p>(M) A requirement that a medical history and physical examination be performed as follows:</p> <p>(i) In accordance with medical staff requirements on history and physical consistent with the scope and complexity of the procedure to be performed.</p> <p>(ii) On each patient admitted by a physician, dentist, or podiatrist who has been granted such privileges by the medical staff or by another member of the medical staff.</p> <p>(iii) Within the time frame specified by the medical staff prior to date of admission and documented in the record with a durable, legible copy of the report and with an update and changes noted in the record on admission in accordance with center policy.</p> <p>Based on medical staff rules and regulations review, patient medical record review and staff interview, the facility failed to ensure that history and physical examinations were either performed or updated on the day of surgery for 7 of 14</p>			S0772	<p>1. Plan offi Correctton Medical staff members were sentt infformatton aboutt tthe requirementt offi a history and physical tto be perfformed on tthe day offi tthe procedure or no greater ttha30 days prior tto tthe procedureAn update mustt be perfformed on tthe</p>		07/28/2011

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	<p>patients. (N1, N4, N7, N10, N11, N12 and N13)</p> <p>Findings:</p> <p>1. at 4:40 PM on 7/25/11, review of the medical staff rules and regulations indicated:</p> <p>a. on page 5, in item d., it read: "A pre-operative medical evaluation and physical examination must be performed and recorded or dictated by an anesthesiologist or surgeon on all patients receiving treatment in the operating rooms immediately before surgery and made part of the medical record."</p> <p>2. review of patient medical records through out the survey process of 7/25/11 to 7/27/11, indicated:</p> <p>a. pt. N1 had a history and physical performed 6/20/11 and surgery on 6/22/11 with no updated noted documented on the history and physical on the day of surgery</p> <p>b. pt. N4 had a history and physical performed on 11/24/10 and surgery on 11/29/10 with with no updated noted documented on the history and physical on the day of surgery</p> <p>c. pt. N7 had:</p> <p>A. a physician office history and physical dated 8/4/10</p> <p>B. a surgery date of 9/8/10</p> <p>C. a brief history and physical form (form # RSC - 300) that was not</p>				<p>datte offi tthe procedure history and physical greater ttha30 days old cannott be updatteda new one mustt be completedt</p> <p>Forms were revised tto ttrigger appropriatte completton offi history and physical infformatton</p> <p>Sttaffi were educattted tto acknowledge ttheir role in sttopping movementt offi tthe patttentt ffirom tthe operative area into tthe operattng rooms untll a history and physical is in tthe medical record</p> <p>Exhibitt(s)</p> <p>Medical record ffiorms</p> <p>Memo tto medical sttaffi members regarding requirementts ffor a histttry and physical</p> <p>2. Preventton:</p> <p>Histttry and physical will be checked by tthe circulattng nurse prior tto tthe patttentt moving into tthe operattng room.</p> <p>3. Responsible</p> <p>Person(s): OIC Coordinattor</p> <p>4. Correctton</p> <p>Completedt</p> <p>a. Sttaffi educattton completted July 28, 2011</p> <p>b. Medical record ffiorms re-design completted August12, 2011</p> <p>c. To be presentted tto governing</p>		

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	complete and had no date documented d. pt. N10 had: A. surgery on 5/11/11 B. a dictated history and physical with a dictation date of 6/8/11 C. a brief History and Physical form (form # RSC - 300) that is not complete e. pt. N11 had: A. Surgery on 9/30/10 B. a progress note from the physician's office dated 9/21/10 that serves as a history and physical C. was lacking an update to the 9/21/10 note on the day of surgery f. pt. N12 had: A. surgery on 6/22/10 B. a letter dated 6/17/10 to the attending/referring physician of the proposed surgery C. no history and physical in the patient chart g. pt. N13 had: A. surgery on 4/29/11 B. a letter dated 4/19/11 to the attending/referring physician related to the proposed surgery C. no history and physical in the patient chart 3. interview with staff member ND at 10:00 AM on 7/27/11 indicated: a. this staff member was unaware of the medical staff rules and regulations b. it was unknown that history and				body on September1, 2011		

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S0780	<p>physical examinations needed an update on the day of surgery</p> <p>c. pts. N12 and N13 have letters to physicians that the surgeon was utilizing as a history and physical, but was not per standards of practice for a history and physical</p> <p>d. pts. N7 and N10 had brief history and physical forms, but the forms were not complete</p> <p>410 IAC 15-2.5-4(b)(3)(N)</p> <p>These bylaws and rules must be as follows:</p> <p>(3) Include, at a minimum, the following:</p> <p>(N) A requirement that all practitioner orders are in writing or acceptable computerized form and must be authenticated by a responsible practitioner as allowed by medical staff policies and within the time frames specified by the medical staff and center policy not to exceed thirty (30) days.</p> <p>Based on policy and procedure review, medical staff rules and regulations review, patient medical record review, and staff interview, the facility failed to ensure that 2 of 5 transfer patients had an order for transfer (N5 and N14).</p> <p>Findings:</p> <p>1. at 4:40 PM on 7/25/11, review of the policy and procedure "Transfers,</p>		S0780	<p>The policy on the transfer of patients was amended to include a requirement for a transfer order by a physician.</p> <p>The medical staff rules and regulations will be reviewed and changed as appropriate</p> <p>Nursing staff and physicians will receive education.</p> <p>A transfer checklist will be developed.</p>		08/26/2011	

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	<p>Hospital" with a policy number of CT-01 and a last revision date of 04/05, indicated:</p> <p>a. the policy does not address obtaining an order to transfer the patient</p> <p>2. at 4:40 PM on 7/25/11, review of the medical staff rules and regulations indicated:</p> <p>a. in "Section 2. Orders", there is nothing related to patient transfers and the need for a physician order for transfer</p> <p>3. review of patient medical records through out the survey process of 7/25/11 to 7/27/11 indicated:</p> <p>a. patients N5 and N14 were transfer patients who were lacking a physician order for transfer</p> <p>4. interview with staff member ND at 11:00 AM on 7/27/11 indicated:</p> <p>a. all transfer patients are to have an order for transfer</p> <p>b. neither the medical staff rules and regulations, nor the transfer policy addresses the need for a practitioner order for transfer of a patient</p>				<p>Exhibitt(s) Transffier policy changed Transffier ffirm changed</p> <p>1. Preventton: Sttaffi will complete a ttransffier ffirm and presentt copy tto tthe QIC coordinattor who will review ttracking mechanism and assure orders are in tthe record</p> <p>2. Responsible Person(s): QIC Coordinattor</p> <p>3. Correctton Completed</p> <p>a. Transffier policy and ffirm changes draffied by August26</p> <p>b. Evaluatton offi changes tto medical sttaffi rules and regulattons completed by August26</p> <p>c. Presenttatton tto governing body on Septtember1, 2011</p>		

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S0840	<p>410 IAC 15-2.5-4(c)(2)</p> <p>(c) The anesthesia service is responsible for all anesthesia administered in the center as follows:</p> <p>(2) A requirement that anesthesia equipment must be checked for operational readiness and safety prior to patient administration. Documentation to that effect shall be included in the patient's medical record.</p> <p>Based upon document review and interview, the facility failed to ensure that anesthesia equipment was checked prior to use on patients in 2 of 12 examples.</p> <p>Findings:</p> <p>1. On 07-25-2011 at 1130 hours, employee #A2 was requested to provide a policy/procedure requiring all anesthesia equipment be checked for safety and operational readiness prior to use on patients and none was provided prior to exit.</p> <p>2. During a review of 12 medical records, 2 records (N3 and N12) were observed to lack documentation of anesthesia equipment checks in the designated location on the anesthesia record.</p> <p>3. During an interview on 07-26-2011 at 1630, employee #A4 confirmed the facility failed to have a policy/procedure</p>		S0840	<p>1. Plan offi Correctton Policy and procedure was written requiring tthe anestthesia equipmentt be checked prior tto each procedure The locatton offi tthis infformatton was on tthe anestthesia ffirm and anestthesia staffi was reminded offi tthe requirementt to conductt tthe check and documentt itt on tthe ffirm</p> <p>Exhibitt(s) Policy on anestthesia equipmentt checks Currentt anestthesia ffirm</p> <p>2. Preventton: Anestthesia equipmentt checks will be confirmed by tthe anestthesia staffi and documentted The medical record will be auditted tto assure documenttatton offi tthe check occurs.</p> <p>3. Responsible Person(s): QIC Coordinattor</p> <p>4. Correctton</p>		08/26/2011	

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S0900	<p>requiring anesthesia equipment checks prior to use on patients.</p> <p>410 IAC 15-2.5-5(a)</p> <p>(a) All patient care services must meet the needs of the patient, within the scope of the service offered, in accordance with acceptable standards of practice. Patient care services must be under the direction of a qualified person or persons. Patient care services must require the following: Based on policy and procedure review, patient medical record review, and staff interview, the facility failed to implement its policy related to the assessment of pain on admission to the facility, for 14 of 14 patient records (N1 through N14).</p> <p>Findings: 1. at 12:05 PM on 7/25/11, review of the policy and procedure "Pain Assessment and Management", with a policy number "CP - 03", indicated: a. under "Policy", it read: "Patients will be assessed initially and periodically to accomplish the goal of effective pain management..." b. under "Guidelines", it reads: "1. Document the patient pain assessment on the preoperative history and upon</p>		S0900	<p>Completed</p> <p>a. Policy off tthe checking off tthe anestthesia equipmentt written by Augustt26, 2011 b. Policy presentt to Governing body att Septtembe1, 2011 meeting</p> <p>1. Plan offi Correctton The pre-operattve nursing care record will be revised tto add a pain assessmentt and managementt documenttatton section</p> <p>Exhibitt(s) Form</p> <p>2. Preventton: Nursing sttaffi will be educatted on tthe assessmentt and managementt offi pain and tthe recording offi tthis assessmentt and managementt in tthe medical record. The medical records will be auditted tto review compliance and sttaffi reeducatted as needed tto achieve ttotall compliance</p> <p>3. Responsible Person(s): QIC coordinattor</p>		08/26/2011	

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	<p>admission to RiverPointe Surgery Center..."</p> <p>2. review of patient medical records through out the survey process of 7/25/11 to 7/27/11, indicated:</p> <p>a. pts. N1 through N14 were lacking documentation of a pain assessment on admission to the facility as required per policy</p> <p>3. interview at 5:10 PM on 7/25/11 with staff member ND indicated:</p> <p>a. this staff member was unaware that the pain policy required a pain assessment on admission</p> <p>b. it was assumed that this documentation would be placed on the "Admission Record" form (form # RSC - 103), but upon review of the form, it was found there is no area for pain documentation</p> <p>c. nursing staff have not been assessing pain level on admission to the facility as policy dictates</p>				<p>4. Correcton Completed</p> <p>a. Pre-operattve nursing care ffirm revised by August6, 2011</p> <p>b. Staffi educatted by August6, 2011</p> <p>c. Form and correcttve actton presentted tto tthe Governing Body on Septtember1, 2011</p>		

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S1040	<p>410 IAc 15-2.5-6(3)(F)</p> <p>Pharmaceutical service must have the following:</p> <p>(3) Written policies and procedures developed, implemented, maintained, and made available to personnel, including, but not limited to, the following:</p> <p>(F) Instructions to the patient on the use of take home medication is the responsibility of the prescribing practitioner.</p> <p>Based upon document review and interview, the facility failed to have a policy/procedure regarding the physician responsibility of instructing the patient (when indicated) on the use of take home medication.</p> <p>Findings:</p> <p>1. On 07-25-2011 at 1130 hours, employee #A2 was requested to provide a policy/procedure regarding dispensing medications to patients while at the facility and none was provided prior to exit.</p> <p>2. The Pharmacy consultant report dated 03-18-2011 indicated the following under the category Samples; Samples stocked for Dr. Boling. These are brought from his office. Patients are not charged for these and are sent home with the patient.</p>		S1040	<p>1. Plan offi Correctton Sending samples offi medicattons home with patientts was stoppped affier tthe pharmacy consultantt broughtt itt to the attention offi tthe stafffi lastt MarchA policy was written tto confirm tthatt no medicattons are dispensed and no samples are given tto patientts by tthe ffacility</p> <p>Exhibitt(s) Policy</p> <p>2. Preventton: Sttaffi was educatted on tthis issue in May 2011. Sttaffi will review tthe newly written policy tthatt confirms tthatt tthere will be no dispensing offi medicatton by tthe ffacility</p> <p>3. Responsible Person(s): QIC Coordinattor</p> <p>4. Correctton</p>		09/09/2011	

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S1182	<p>Also samples stocked for Dr. Meyer (Ciprodex). These samples are used in surgery and remainder is sent home with patient. Patients are not charged for these.</p> <p>3. On 07-27-2011 at 1215, employee #A6 confirmed the facility failed to have a policy/procedure for the physician responsibility of instructing the patient (when indicated) on the use of take home medication.</p> <p>410 IAC 15-2.5-7(c)(2)</p> <p>(c) A safety management program must include, but not be limited to, the following:</p> <p>(2) An ongoing center-wide process to evaluate and collect information about hazards and safety practices to be reviewed by the committee.</p> <p>Based upon document review and interview, the facility failed to document an ongoing, center-wide program which collected and evaluated information about hazards and safety practices.</p> <p>Findings:</p> <p>1. The RiverPointe Surgery Center Medical Staff Bylaws (last reviewed/approved 07-28-2010) indicated the following; The Medical Quality</p>		S1182	<p>Completed</p> <p>a. Policy written by August 26</p> <p>b. Policy presented to Governing Body for approval at September 2011 meeting</p> <p>c. Staff educated on newly written and approved policy by September 9, 2011</p> <p>1. Plan of Correction</p> <p>A safety survey policy and form was developed. A safety survey will be completed at least once a quarter. The results of the survey will be presented to the MQIC committee at its quarterly meeting and a summary will be presented to the Governing Body at its quarterly meeting.</p> <p>Exhibit(s)</p> <p>Safety survey policy</p> <p>Safety survey form</p>		08/26/2011	

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	<p>Improvement Committee (MQIC) shall also incorporate the functions of a Safety Committee. These functions shall include, but not be limited to: ... (9)(a) ... procedures for identifying workplace hazards, including scheduled periodic inspections and reviewing the results of such inspections ... [and] ... (10). ensuring that records of scheduled and periodic inspections to identify unsafe conditions and practices are kept for three years. These records must identify the persons conducting the inspection, the unsafe conditions and work practices that have been identified, and the action taken to correct these unsafe conditions and work practices.</p> <p>2. Review of the MQIC meeting minutes for 2010 and 2011 failed to indicate a report by the Safety Committee for 6 of 6 meetings, failed to document any recommendations (if indicated) regarding review of Incident Reports (Quality Monitor Report) for 6 of 6 meetings, and failed to document any discussion or review of periodic scheduled facility safety inspections conducted by a member or members of the Safety Committee for 6 of 6 meetings.</p> <p>3. On 07-26-2011 at 1203 hours, employee #A1 was requested to provide records of periodic facility safety</p>				<p>2. Prevention: A safety survey will be conducted quarterly. A list of items to be completed quarterly will be maintained and reviewed for completeness.</p> <p>3. Responsible Person(s): Executive Assistant</p> <p>4. Correction Completed</p> <p>a. Policy and form were developed by August 19, 2011</p> <p>b. Safety survey will be completed by August 26, 2011</p> <p>c. Governing body will be presented with survey results at September 1, 2011 meeting</p>		

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CENTERS FOR MEDICARE & MEDICAID SERVICES

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S1198	<p>inspections performed by the Safety Committee and none was provided prior to exit.</p> <p>4. On 07-26-2011 at 1600, employee #A6 confirmed that the MQIC committee was not reviewing facility safety inspections to identify, evaluate, and remediate environmental safety issues and problems for the facility.</p> <p>410 IAC 15-2.5-7(c)(6)</p> <p>(c) A safety management program must include, but not be limited to, the following:</p> <p>(6) Emergency and disaster preparedness coordinated with appropriate community, state, and federal agencies.</p> <p>Based upon document review and interview, the facility failed to establish an Emergency and Disaster Preparedness plan in cooperation with local, state, and federal agencies.</p> <p>Findings:</p> <p>1. On 07-25-2011 at 1130 hours, employee #A2 was requested to provide documentation indicating coordination of services with area, state, and federal disaster agencies and none was provided prior to exit.</p> <p>2. Review of the existing Disaster Plan</p>			S1198	<p>1. Plan offi Correctton</p> <p>The ffiacility will prepare a comprehensive emergency managementt and disaster preparedness plan tto deffine ittts acttvittes during an emergency and a disaster The ffiacility contacted tthe local healthth departmentt emergency planning departmentt tto inquire aboutt alerttng tthe departmentt tto tthe surgery centter's emergency managementt and disaster preparedness acttvittes and received a reply tthat coordination acttvittes and planning were under review by tthe county health departmentt and tthe ffiacility would be contacted latter</p>		09/09/2011

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	<p>documents failed to indicate any relationship or attempts to coordinate a response with the facility landlord and 40% shareholder Elkhart General Hospital.</p> <p>3. During an interview on 07-27-2011 at 1015 hours, employee #A6 confirmed the facility was not currently associated with any local, regional (District 2), state, or federal disaster agencies.</p>				<p>Exhibit(s) Elkhart County Health Department communication</p> <p>2. Prevention: The facility will educate its staff and provide information to the county about its activities when an emergency or disaster occurs. The plan will be reviewed periodically and any changes submitted to the county health department. The facility will practice its response to emergencies and disasters as appropriate to its planned activities for responding.</p> <p>3. Responsible Person(s): QIC Coordinator</p> <p>4. Correction Completed</p> <p>a. A comprehensive emergency management and disaster preparedness plan will be completed and presented to the governing body at the September, 2011 meeting.</p> <p>b. Once approved by the governing body, the plan will be presented to the Elkhart County Health Department by September 2011.</p> <p>c. The facility staff will be educated on emergency and disaster response. Quarterly drills will be conducted on at least response to a</p>		

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S1210	<p>410 IAC 15-2.5-8(c)(1)</p> <p>(c) All centers shall comply with all regulations set forth in this rule and with 410 IAC 5, when radiology services are provided on-site by the center, including, but not limited to the following:</p> <p>(1) Radiology services must be supervised by a radiologist or radiation oncologist.</p> <p>Based upon document review and interview, the facility failed to ensure its radiology services were supervised by a radiologist or radiation oncologist.</p> <p>Findings:</p> <p>1. The policy/procedure Radiation Safety (revised 05-2005) failed to indicate a radiologist or radiation oncologist was required to supervise the provision of radiology services or otherwise performed a periodic review of radiologic policies, procedures and quarterly radiation dosimetry badge reports for the center.</p> <p>2. On 07-26-2011 at 1200 hours, employee #A1 confirmed that he had reviewed and signed the Radiation Safety policy in 2005 and the facility was not utilizing a radiologist or radiation oncologist for a periodic review of the radiologic services.</p>			S1210	<p>ffire in tthe ffacility</p> <p>1. Plan of Correction: An agreement with a radiologist will be signed for the oversight of radiology services provided. Exhibit(s)Radiologist agreement for oversight of radiology services 2. Prevention: The agreement will be monitored for renewal. The reports on oversight by the radiologist will be included in the MQIC meeting and summary presented to the Governing Body quarterly. 3. Responsible Person(s): Executive Assistant 4. Correction Completed: a. Radiology agreement was completed on July 26, 2011b. To presented to the governing body for approval.</p>		07/27/2011

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